

REMARKS

In the Office Action dated October 1, 2003, all pending claims 1-17 were rejected. In response thereto, claims 1, 13 and 16 have been amended and new claims 18-21 have been added. Support for new claims 18-21 can be found on page 76, line 3 through page 79, line 21. In addition, the Specification has been amended to correct typographical errors. None of the amendments made herein constitute the addition of new matter. Upon entry of this Amendment, claims 1-21 remain pending for the Examiner's consideration. Reconsideration is respectfully requested in light of the following remarks.

Rejections under 35 U.S.C. §103(a) addressed

Claims 1-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 112464420 combined with Royer (WO 98/00161) in view of Sims et al. and Shah et al. for the reasons discussed below.

The Examiner asserts that JP 11246420 teaches a wound-healing accelerator comprising a fibrin gel containing platelets, and further teaches that the gels may be moldable and that the platelets should be autologous. The Examiner further asserts that WO 98/00161 teaches a fibrin-based matrix that may be molded, Sims teaches that fibrin monomers can be polymerized into moldable gels, and Shah compares fibrin gels and plasma clots with platelet rich plasma clots. From this the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce autologous platelet rich plasma gels for filling wound defects because the benefit of fibrin gels and platelet-filled fibrin clots in treating wounds is well recognized by both WO 98/00161 and JP 11246420. This rejection is respectfully traversed.

Independent claim 1 has been amended herein to further define the autologous platelet gel as comprising thrombin and an anticoagulated blood component isolated from an individual to whom the platelet gel is to be applied, wherein the thrombin is isolated from a portion of said anticoagulated blood component. In addition, independent claim 13 was similarly amended to recite a method of making an autologous gel from autologous thrombin and an autologous anticoagulated blood component, wherein the thrombin is isolated from a portion of said anticoagulated blood component. It is asserted that the cited references, either alone or in combination, do not teach or suggest the autologous platelet gel as recited in amended claim 1 or the method of making an autologous platelet gel as recited in amended claim 13, wherein both of the components used to form the gel are obtained from the same

fraction of an autologous blood sample.

More specifically, JP 11246420 does not expressly or inherently teach or suggest all the elements as set forth in claims 1-17. Rather, JP 1124620 teaches a wound healing accelerator comprising fibrin and platelets, which is a different composition than the autologous platelet gel of claims 1-17. Further, there is no suggestion in JP 1124620 to include an inactive blood component in the wound healing accelerator formulation, nor is there any teaching or suggestion in JP 1124620 of a thrombin component that is isolated from a portion of an autologous anticoagulated blood component. Rather, JP 1124620 merely states that thrombin can optionally be added as a stimulant (paragraph [0024]) but does not even provide a source for the thrombin. Thus, not only does the JP 1124620 wound healing accelerator contain different elements than the autologous platelet gel of claims 1-17, but JP 1124620 does not even teach or suggest a method of preparing an autologous platelet get from thrombin and an anticoagulated blood component as set forth in claims 13-17.

Royer similarly does not teach or suggest every element of claims 1-17, either alone or in combination with JP 1124620. Royer teaches a method synthesizing a drug delivery system which comprises mixing fibrinogen, thrombin, medicinal, and other optional components such as inhibitors of fibrinolysis, Factor XIII, albumin and collagen, and then shaping this mixture. However, as with JP 1124620, Royer is deficient in teaching or even suggesting an anticoagulated blood component in his drug delivery system. Further, Royer does not teach or suggest a thrombin component that is isolated from a portion of the anticoagulated blood component. Therefore, not only does the Royer composition contain different elements than the autologous platelet gel of claims 1-17, but Royer does not even teach or suggest a method of preparing an autologous platelet get from thrombin and an anticoagulated blood component as set forth in claims 13-17.

Accordingly, even if there was a motivation to combine JP 1124620 and Royer, the combination still would not teach or suggest an autologous platelet gel comprising an anticoagulated blood component and thrombin, wherein the thrombin is isolated from a portion of the anticoagulated blood component as set forth in claims 1-12, nor would the combination teach or suggest a method of making such an autologous platelet gel as set forth in claims 13-17.

Sims is cited for teaching that fibrin monomers can be polymerized into moldable gels and used for the encapsulation of isolated chondrocytes and autogenous grafts for facial skeletal and soft-tissue augmentation. However, it is asserted that Sims adds nothing to the

combination of JP 1124620 and Royer that would render the present invention obvious. Sims describes a method of entrapping isolated chondrocytes in a fibrin glue by combining the chondrocytes with bovine thrombin and cryoprecipitated fibrinogen (see Abstract). As discussed in the Specification on page 8, lines 21-24, and page 9, lines 17-28, serious problems are associated with the use of bovine thrombin, since bovine thrombin has been known to carry infectious agents such as spongiform encephalopathy, as well as other viruses pathogenic to mammals. In addition, bovine thrombin can cause hemophilia in patients. Thus, in contrast to Sims, the present invention eliminates the need for bovine thrombin since the thrombin component of the presently claimed autologous platelet gel is isolated from a portion of an autologous anticoagulated blood component. Further, Sims does not teach or suggest adding an autologous blood component to autologous thrombin (which was prepared from a portion of the anticoagulated blood component) to prepare an autologous platelet gel. Therefore, regardless of the fact that Sims teaches that fibrin monomers can be polymerized into moldable gels, the combination of Sims with the teachings of JP 1124620 and Royer does not render the present invention obvious.

Shah is cited for disclosing a comparison of fibrin gels and plasma clots with platelet rich plasma clots, showing that platelet rich plasma clots have a higher elastic resistance to deformation than fibrin clots. However, it is asserted that the teachings of Shah add nothing to the combination of JP 1124620 and Royer that would render the present invention obvious. Shah describes rheologic studies of coarse fibrin clots and clots of human plasma both with and without platelets by combining bovine thrombin with either purified fibrinogen (isolated from platelet poor plasma) or whole blood plasma (see page 263, first column, third paragraph and page 264, first column, second paragraph). This is in contrast to the present invention, which not only combines autologous thrombin with an anticoagulated blood component, but in addition uses an autologous thrombin that is isolated from a portion of the same anticoagulated blood component. Thus, even if there were motivation to combine Shah with the teachings of JP 1124620 and Royer, the combination still would not render the present invention obvious.

CONCLUSIONS

It is believed that all the claims now pending in this patent application, as amended and described above, are now allowable, which action is respectfully requested. The fee required for the filing of a Petition for an Extension of Time accompanies this response.

Should any additional fees be required, please charge Deposit Account No. 50-1123. The Examiner is asked to kindly contact the undersigned by telephone should any outstanding issues remain.

Respectfully submitted,

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Dated


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